

IFW
PATENT

Case Docket No. NIH214.001C1
Date: August 31, 2004

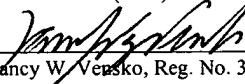
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Whitehead et al.
Appl. No. : 10/719,547
Filed : November 21, 2003
For : DEVELOPMENT OF
MUTATIONS USEFUL FOR
ATTENUATING DENGUE
VIRUSES AND CHIMERIC
DENGUE VIRUSES
Examiner : Unknown
Group Art Unit : 1648

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August 31, 2004

(Date)


Nancy W. Vensko, Reg. No. 36,298

TRANSMITTAL LETTER

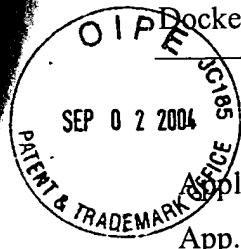
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Dear Sir:

Enclosed for filing in the above-identified application are:

- (X) An Information Disclosure Statement.
- (X) A PTO Form 1449 with seventy-six (76) references.
- (X) The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.
- (X) Return prepaid postcard.


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**INFORMATION DISCLOSURE STATEMENT**

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Dear Sir:

Enclosed is form PTO-1449 listing 76 references. Copies of disclosed U.S. patents and/or publications are not included pursuant to PTO waiver of the requirement under 37 C.F.R. § 1.98(a)(2)(i) for applications filed after June 30, 2003. Copies of other references, if listed, are enclosed.

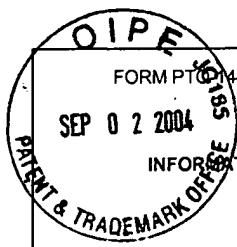
This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required in accordance with 37 C.F.R. § 1.97(b)(3). If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 8/31/04

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FORM PTO 1449 SEP 02 2004 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (USE SEVERAL SHEETS IF NECESSARY)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE ATTY. DOCKET NO. NIH214.001C1	APPLICATION NO. 10/719,547
	APPLICANT Whitehead et al.	
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	1.	US 6,074,865	06/13/2000	Kelly et al.			
	2.	US 6,455,509	09/24/2002	Kochel et al.			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)	
3.	Angsubhakorn, S. et al. 1994 "Dengue-3 (16562) PGMK 33 vaccine: neurovirulence, viremia and immune responses in <i>Macaca fascicularis</i> ," <i>Southeast Asian J. Trop. Med. Public Health</i> 25:554-559.	
4.	Bancroft W.H. et al. 1981 "Dengue-2 vaccine: virological, immunological, and clinical responses of six yellow fever-immune recipients," <i>Infect. Immun.</i> 31:698-703.	
5.	Bancroft, W.H. et al. 1984 "Dengue virus type 2 vaccine: reactogenicity and immunogenicity in soldiers." <i>J. Infect. Dis.</i> 149:1005-1010.	
6.	Bhamarapravati, N. et al. 2000 "Live attenuated tetravalent dengue vaccine." <i>Vaccine</i> 18(Suppl. 2):44-47.	
7.	Bhamarapravati, N. et al. 1997 "Live attenuated tetravalent dengue vaccine, p. 367-377. In D. J. Gubler, and G. Kuno (ed.), <i>Dengue and Dengue Hemorrhagic Fever</i> . CAB International, New York, N.Y.	
8.	Bhamarapravati N. et al. 1987 "Immunization with a live attenuated dengue-2-virus candidate vaccine (16681-PDK 53): clinical, immunological and biological responses in adult volunteers," <i>Bull World Health Organ.</i> 65:189-195.	
9.	Blaney J.E. Jr., et al. 2001 "Chemical mutagenesis of dengue virus type 4 yields mutant viruses which are temperature sensitive in vero cells or human liver cells and attenuated in mice." <i>J. Virol.</i> 75:9731-9740.	
10.	Blok, J. et al. 1992 "Comparison of a dengue-2 virus and its candidate vaccine derivative: sequence relationships with the flaviviruses and other viruses." <i>Virology</i> 187:573-590.	
11.	Bray, M. et al. 1996 "Monkeys immunized with intertypic chimeric dengue viruses are protected against wild-type virus challenge," <i>J. Virol.</i> 70:4162-4166.	
12.	Bray, M. et al. 1991 "Construction of intertypic chimeric dengue viruses by substitution of structural protein genes," <i>PNAS USA</i> 88:10342-10346.	
13.	Burke, D.S. et al. 1988 "A prospective study of dengue infections in Bangkok." <i>Am. J. Trop. Med. Hyg.</i> 38:172-180.	

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*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.	

<p style="text-align: center;">O I P E SEP 02 2004 (USE SEVERAL SHEETS IF NECESSARY)</p> <p style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p>	ATTY. DOCKET NO. NIH214.001C1	APPLICATION NO. 10/719,547
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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
14.	Butrapet, S. et al. 2000 "Attenuation markers of a candidate dengue type 2 vaccine virus, strain 16681 (PDK-53), are defined by mutations in the 5' noncoding region and nonstructural proteins 1 and 3." <i>J. Virol.</i> 74 :3011-3019.
15.	CDC, 2000 "Public Health Dispatch: Outbreak of poliomyelitis – Dominican Republic and Haiti, 2000" <i>MMWR Morb. Mortal Wkly. Rep.</i> 49 :1094-1104.
16.	Chambers, T.J. et al. 1999 "Yellow fever/Japanese encephalitis chimeric viruses: construction and biological properties," <i>J. Virol.</i> 73 :3095-3101.
17.	Chang, G.-J. 1997 "Molecular biology of dengue viruses, p. 175-198. In D. J. Gubler, and G. Kuno (ed.), <u>Dengue and Dengue Hemorrhagic Fever</u> . CAB International, New York, N.Y.
18.	Chen, W. et al. 1995 "Construction of intertypic chimeric dengue viruses exhibiting type 3 antigenicity and neurovirulence for mice," <i>J. Virol.</i> 69 :5186-5190.
19.	Cole, G.A. et al. 1969 "Pathogenesis of type 1 dengue virus infection in suckling, weanling and adult mice. 1. The relation of virus replication to interferon and antibody formation." <i>Am. J. Epidemiol.</i> 89 :669-680.
20.	Cole, G.A. et al. 1973 "Pathogenesis of type 1 dengue virus infection in suckling, weaning and adult mice. II. Immunofluorescent and histological studies." <i>J. Comp. Pathol.</i> 83 :243-252.
21.	Couvelard, A. et al. 1999 "Report of a fatal case of dengue infection with hepatitis: demonstration of dengue antigens in hepatocytes and liver apoptosis." <i>Hum. Pathol.</i> 30 :1106-1110.
22.	Dunster, L.M. et al. 1999 "Molecular and biological changes associated with HeLa cell attenuation of wild-type yellow fever virus." <i>Virology</i> 261 :309-318.
23.	Durbin A.P. et al. 2001 "Attenuation and immunogenicity in humans of a live dengue virus type-4 vaccine candidate with a 30 nucleotide deletion in its 3'-untranslated region." <i>Am. J. Trop. Med. Hyg.</i> 65 :405-13.
24.	Eckels, K.H. et al. 1980 "Dengue-2 vaccine: preparation from a small-plaque virus clone." <i>Infect. Immun.</i> 27 :175-180.
25.	Eckels, K.H. et al. 1984 "Selection of attenuated dengue 4 viruses by serial passage in primary kidney cells. V. Human response to immunization with a candidate vaccine prepared in fetal rhesus lung cells." <i>Am. J. Trop. Med. Hyg.</i> 33 :684-689.
26.	Edelman, R. et al. 1994 "A live attenuated dengue-1 vaccine candidate (45AZ5) passaged in primary dog kidney cell culture is attenuated and immunogenic for humans." <i>J. Infect. Dis.</i> 170 :1448-1455.
27.	Gubler, D.J. et al. 1998 "Dengue and dengue hemorrhagic fever," <i>Clin. Microbiol. Rev.</i> 11 :480-496.
28.	Gubler, D. J. 1999 "Impact of dengue/dengue hemorrhagic fever on the developing world." <i>Adv. Virus Res.</i> 53 :35-70.
29.	Guirakhoo, F. et al. 2000 "Recombinant chimeric yellow fever-dengue type 2 virus is immunogenic and protective in nonhuman primates." <i>J. Virol.</i> 74 :5477-5485.
30.	Halstead, S.B. et al. 1977 "Dengue viruses and mononuclear phagocytes. II. Identity of blood and tissue leukocytes supporting in vitro infection." <i>J. Exp. Med.</i> 146 :218-229.

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	31.	Halstead, S.B. et al. 1969 "Dengue and chikungunya virus infection in man in Thailand, 1962-1964. IV. Epidemiologic studies in the Bangkok metropolitan area." <i>Am. J. Trop. Med. Hyg.</i> 18 :997-1021.	
	32.	Hoke, C.H. Jr. et al. 1990. "Preparation of an attenuated dengue 4 (341750 Carib) virus vaccine. II. Safety and immunogenicity in humans," <i>Am J. Trop. Med. Hyg.</i> 43 :219-226.	
	33.	Holbrook, M.R. et al. 2000 "The French neurotropic vaccine strain of yellow fever virus accumulates mutations slowly during passage in cell culture." <i>Virus Res.</i> 69 :31-39.	
	34.	Huang, C.Y. et al. 2000 "Chimeric dengue type 2 (vaccine strain PDK-53)/dengue type 1 virus as a potential candidate dengue type 1 virus vaccine." <i>J. Virol.</i> 74 :3020-3028.	
	35.	Huerre, M.R. et al. 2001 "Liver histopathology and biological correlates in five cases of fatal dengue fever in Vietnamese children." <i>Virchows Arch.</i> 438 :107-115.	
	36.	Igarashi, A. 1997 "Impact of dengue virus infection and its control," <i>FEMS Immunol. Med. Microbiol.</i> 18 :291-300.	
	37.	Innis, B.L. 1995 "Dengue and dengue hemorrhagic fever, p. 103-146. In J. S. Porterfield (ed.), <i>Exotic Viral Infections</i> . Chapman and Hall, London, United Kingdom.	
	38.	Innis, B L. et al. 1988 "Virulence of a live dengue virus vaccine candidate: a possible new marker of dengue virus attenuation." <i>J. Infect. Dis.</i> 158 :876-880.	
	39.	Jennings, A.D. et al. 1994 "Analysis of a yellow fever virus isolated from a fatal case of vaccine-associated human encephalitis." <i>J. Infect. Dis.</i> 169 :512-518.	
	40.	Kalayanarooj, S. et al. 1997 "Early clinical and laboratory indicators of acute dengue illness." <i>J. Infect. Dis.</i> 176 :313-321.	
	41.	Kanesa-thasan, N. et al. 2001 "Safety and immunogenicity of attenuated dengue virus vaccines (Aventis Pasteur) in human volunteers." <i>Vaccine</i> 19 :3179-3188.	
	42.	Kraiselburd E. et al. 1985 "Quantity of dengue virus required to infect rhesus monkeys," <i>Trans. R. Soc. Trop. Med. Hyg.</i> 79 :248-251.	
	43.	Kuo, C.H. et al. 1992 "Liver biochemical tests and dengue fever." <i>Am. J. Trop. Med. Hyg.</i> 47 :265-270.	
	44.	Kurane, I. et al. 1990 "Dengue-2 virus infection of human mononuclear cell lines and establishment of persistent infections." <i>Arch. Virol.</i> 110 :91-101.	
	45.	Lai, C.J. et al. 1991 "Infectious RNA transcribed from stably cloned full-length cDNA of dengue type 4 virus," <i>Proc Natl Acad Sci USA</i> 88 :5139-5143.	
	46.	Lee, E. et al. 1997 "Changes in the dengue virus major envelope protein on passaging and their localization on the three-dimensional structure of the protein." <i>Virology</i> 232 :281-290.	
	47.	Libraty, D.H. et al. 2001 "Human dendritic cells are activated by dengue virus infection: enhancement by gamma interferon and implications for disease pathogenesis." <i>J. Virol.</i> 75 :3501-3508.	
	48.	Lin, Y.L. et al. 1998 "Study of dengue virus infection in SCID mice engrafted with human K562 cells." <i>J. Virol.</i> 72 :9729-9737.	
	49.	Lin, Y.L. et al. 2000 "Infection of five human liver cell lines by dengue-2 virus." <i>J. Med. Virol.</i> 60 :425-431.	

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50.	Marianneau, P. et al. 1996 "Dengue 1 virus binding to human hepatoma HepG2 and simian Vero cell surfaces differs." <i>J. Gen. Virol.</i> 77 :2547-2554.		
51.	Martin, J. et al. 2000 "The vaccine origin of the 1968 epidemic of type 3 poliomyelitis in Poland," <i>Virology</i> 278 :42-49.		
52.	McKee, K.T., Jr. et al. 1987 "Lack of attenuation of a candidate dengue 1 vaccine (45AZ5) in human volunteers." <i>Am. J. Trop. Med. Hyg.</i> 36 :435-442.		
53.	Men, R. et al. 1996 "Dengue type 4 virus mutants containing deletions in the 3' noncoding region of the RNA genome: analysis of growth restriction in cell culture and altered viremia pattern and immunogenicity in rhesus monkeys." <i>J. Virol.</i> 70 :3930-3937.		
54.	Mohan, B. et al. 2000 "Hepatic dysfunction in childhood dengue infection." <i>J. Trop. Pediatr.</i> 46 :40-43.		
55.	Monath, T.P. et al. 1999 "Recombinant, chimaeric live, attenuated vaccine (ChimeriVax™) incorporating the envelope genes of Japanese encephalitis (SA14-14-2) virus and the capsid and nonstructural genes of yellow fever (17D) virus is safe, immunogenic and protective in non-human primates," <i>Vaccine</i> 17 :1869-1882.		
56.	Murgue, B. et al. 2000 "Prospective study of the duration and magnitude of viraemia in children hospitalized during the 1996-1997 dengue-2 outbreak in French Polynesia," <i>J. Med. Virol.</i> 60 :432-438.		
57.	Nakabayashi, H. et al. 1982 "Growth of human hepatoma cell lines with differentiated functions in chemically defined medium." <i>Cancer Res.</i> 42 :3858-3863.		
58.	Ni, H. et al. 1995 "Molecular basis of attenuation of neurovirulence of wild-type Japanese encephalitis virus strain SA14." <i>J. Gen. Virol.</i> 76 :409-413.		
59.	Pletnev, A.G. et al. 1998 "Attenuation of the Langat tick-borne flavivirus by chimerization with mosquito-borne flavivirus dengue type 4," <i>PNAS USA</i> 95 :1746-1751.		
60.	Puri, B. et al. 1997 "Molecular analysis of dengue virus attenuation after serial passage in primary dog kidney cells." <i>J. Gen. Virol.</i> 78 :2287-2291.		
61.	Rosen, L. et al. 1999 "Detection of dengue virus RNA by reverse transcription-polymerase chain reaction in the liver and lymphoid organs but not in the brain in fatal human infection." <i>Am. J. Trop. Med. Hyg.</i> 61 :720-724.		
62.	Sabin, A.B. et al. 1945 "Production of immunity to dengue with virus modified by propagation in mice," <i>Science</i> 101 :640-642.		
63.	Sabin, A.B. 1952 "Research on dengue during World War II," <i>Am. J. Trop. Med. Hyg.</i> 1 :30-50.		
64.	Sabin, A. 1955 "Recent advances in our knowledge of dengue and sandfly fever," <i>Am. J. Trop. Med. Hyg.</i> 4 :198-207.		
65.	Scott, R.M. et al. 1980 "Isolation of dengue viruses from peripheral blood leukocytes of patients with hemorrhagic fever." <i>J. Infect. Dis.</i> 141 :1-6.		
66.	Thein, S. et al. 1997 "Risk factors in dengue shock syndrome." <i>Am. J. Trop. Med. Hyg.</i> 56 :566-572.		
67.	Theofilopoulos, A.N. et al. 1976 "Replication of dengue-2 virus in cultured human lymphoblastoid cells and subpopulations of human peripheral leukocytes." <i>J. Immunol.</i> 117 :953-961.		

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	68.	Troyer, J.M. et al. 2001 "A live attenuated recombinant dengue-4 virus vaccine candidate with restricted capacity for dissemination in mosquitoes and lack of transmission from vaccinees to mosquitoes," <i>Am. J. Trop. Med. Hyg.</i> 65 :414-419.	
	69.	Valle, R.P et al. 1998 "Mutagenesis of the NS3 protease of dengue virus type 2." <i>J. Virol.</i> 72 :624-632.	
	70.	Vaughn D.W., et al. 2000 "Dengue viremia titer, antibody response pattern, and virus serotype correlate with disease severity," <i>J. Infect. Dis.</i> 181 :2-9.	
	71.	Vaughn, D.W. et al. 1996 "Testing of a dengue 2 live-attenuated vaccine (strain 16681 PDK 53) in ten American volunteers." <i>Vaccine</i> 14 :329-336.	
	72.	Wahid, S.F. et al. 2000 "A comparison of the pattern of liver involvement in dengue hemorrhagic fever with classic dengue fever." <i>Southeast Asian J. Trop. Med. Public Health</i> 31 :259-263.	
	73.	Wang, E. et al. 1995 "Comparison of the genomes of the wild-type French viscerotropic strain of yellow fever virus with its vaccine derivative French neurotropic vaccine." <i>J. Gen. Virol.</i> 76 :2749-2755.	
	74.	Watts, D.M. et al. 1982 "Evaluation of <i>Toxorhynchites splendens</i> (Diptera:Culicidae) as a bioassay host for dengue viruses," <i>J. Med. Entomol.</i> 19 :54-59.	
	75.	Wisseman C.L. Jr., et al. 1963 "Attenuated living type 1 dengue vaccines," <i>Am J. Trop. Med. Hyg.</i> 12 :620-623.	
	76.	Wu, S.J. et al. 2000 "Human skin Langerhans cells are targets of dengue virus infection." <i>Nat. Med.</i> 6 :816-820.	

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